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REMINDERS ON GOOD CLINICAL PRACTICE (GCP)

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CONTENT OUTLINE

01 Introduction to GCP
02 Institutional Review Boards
03 Informed Consent
04 Confidentiality and Privacy
05 Participant Safety and Adverse Events
06 Quality Assurance
07 The Research Protocol
08 Documentation and Record-keeping
09 Research Misconduct
10 Roles and Responsibilities
11 Recruitment and Retention
12 Investigational New Drugs

What is GCP?

Good Clinical Practice (GCP) is an international ethical and scientific standard for conducting biomedical and behavioral research involving human participants. The objective of this guideline is to provide a unified standard across the European Union (EU), Japan, the United States, Canada, and Switzerland to facilitate the mutual acceptance of data from clinical trials by Regulatory Authorities.

The current system of Good Clinical Practice has evolved, in part, in response to revelations of past episodes in which research participants were grossly abused. Exposure of these incidents provided much of the momentum for the development of regulations and ethical guidelines on the protection of human research participants.

This training is important for all staff involved in Clinical Research and ensures an understanding of the principles adopted in the research.

- GCP is widely accepted and expected in all research involving human participants.
- GCP is not specific to a protocol, but rather is general and applicable to all protocols.

Why is GCP training necessary?

GCP Guidelines

The purpose of the ICH GCP guidelines is twofold:

- To ensure that the rights, safety, and confidentiality of participants in clinical trials are protected.
- To ensure that the data collected in clinical trials, as well as the reported results of clinical trials, are accurate and credible.

The principles in this guideline may be applied to all clinical investigations involving human participants, such as those involving an investigational product, a marketed drug, a medical device, or a behavioral intervention.

ICH GCP Principles

- **Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).**
- **Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial participant and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.**
- **The rights, safety, and well-being of trial participants are the most important considerations and should prevail over the interests of science and society.**
- **The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.**

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ICH GCP Principles

- **Clinical trials should be scientifically sound and described in a clear, detailed protocol.**
- **A trial should be conducted in compliance with a protocol that has received prior institutional review board (IRB) approval.**
- **The medical care given to, and medical decisions made on behalf of, participants should always be the responsibility of a qualified physician or, when appropriate, a qualified dentist.**
- **Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).**
- **Freely given informed consent should be obtained from every participant prior to clinical trial participation.**
- **All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation, and verification.**

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ICH GCP Principles

- **The confidentiality of records that could identify participants should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).**
- **Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practices (GMP). They should be used in accordance with the approved protocol.**
- **Systems with procedures that assure the quality of every aspect of the trial should be implemented.**

INSTITUTIONAL REVIEW BOARDS

The purpose of an Institutional Review Board (IRB) is to safeguard the rights, safety, and well-being of all human research participants.

- To approve a research protocol, the IRB must ensure that:
  - Risks to participants are minimized.
  - Risks to participants are reasonable in relation to anticipated benefits.
  - The selection of participants is equitable.
  - Informed consent is properly obtained and documented.
  - Adequate provision is made for monitoring the data collected to ensure the safety of participants.
  - Adequate provision is made to protect participants and maintain the confidentiality of data
  - Additional safeguards are included for vulnerable populations.

INFORMED CONSENT

Study Purpose

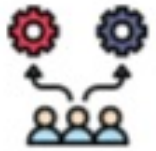
Study Treatment and Randomization

Study Procedures

Risks of Taking Part in the Study

Benefits of taking part in the study

INFORMED CONSENT



Alternatives to taking part in the study

Costs of participation and compensation in the event of injury

Payment for taking part in the study

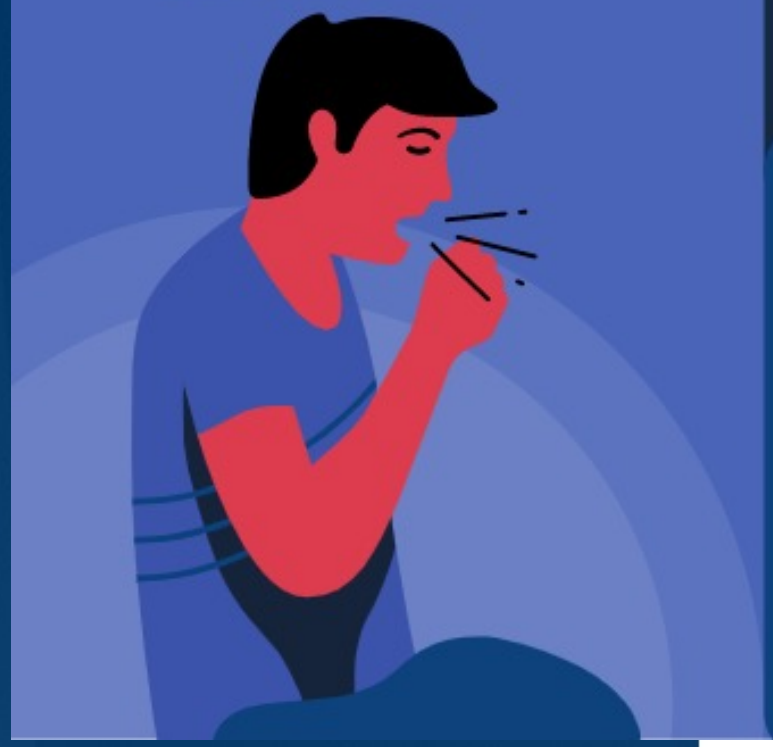
Voluntary nature of study

Confidentiality and Privacy

In general, ALL records of the identity, diagnosis, prognosis, or treatment of any person that are maintained in connection with alcohol or drug abuse prevention, education, training, treatment, rehabilitation, or research must be kept confidential.

However, the regulations identify certain exceptions to the confidentiality requirements. Information in a participant's medical record can be disclosed.

Participant Safety and Adverse Events



The safety and well-being of study participants must be safeguarded at all times during the conduct of a clinical research study.

Adverse Events

any "untoward medical occurrence" in a person who receives a drug while participating in a clinical study. The occurrence need not be causally related to the drug treatment.

Generally, all AEs and SAEs should be followed up until they have resolved or stabilized.

Data and safety monitoring must occur periodically throughout every study to protect participant safety and ensure the integrity of study data, for example, by the Data and Safety Monitoring Board for a clinical trial.

Quality Assurance

Consists of planned, systematic activities conducted to ensure that a trial is performed—and that trial data are generated, documented, and reported—in compliance with the protocol and with Good Clinical Practice (GCP) and all other applicable regulatory requirement(s).

- The purposes of monitoring are to verify that:
  - The rights and well-being of human participants are protected.
  - Reported trial data are attributable, legible, contemporaneous, original, accurate, and complete.
  - The trial is conducted in compliance with the currently approved protocol (including any amendments), as well as with GCP and all other applicable regulatory requirement(s).

Research Protocol

Standardization of procedures

Research that is not conducted in a standardized manner is unethical because it may put research participants at risk while yielding invalid data.

Research Staff

All research staff involved in a clinical study must be familiar with, and must strictly adhere to, the procedures described in the research protocol.

Approved by the IRB

The research protocol provides a plan for the essential aspects of the proposed research.

Protocol Amendment

Amendments must be approved by the IRB before they can be implemented, unless there is an immediate safety concern for participants.

Documentation & Record-Keeping

- Every aspect of a clinical study must be documented in order to obtain useful data and demonstrate compliance with Good Clinical Practice (GCP) standards and with all applicable regulations.
- Sponsors may require specific documentation in addition to the list of essential documents specified by GCP.
- Source documents are original documents created during a clinical study, from which study data are obtained.
- The purpose of CRFs is to gather study data in a standardized format so that the data can be entered into a computerized database and analyzed. All of the information needed to complete the data analyses used to assess the outcomes of the study is recorded in the CRFs.

Research misconduct

Federal Policy defines Research Misconduct as...

"fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results."

Generally, the response to an allegation of research misconduct has three stages:

- Inquiry (to assess the facts of the allegation).
- Investigation (if the inquiry provides adequate basis for one).
- Adjudication (imposing of suitable penalties if the allegation is found to have merit).

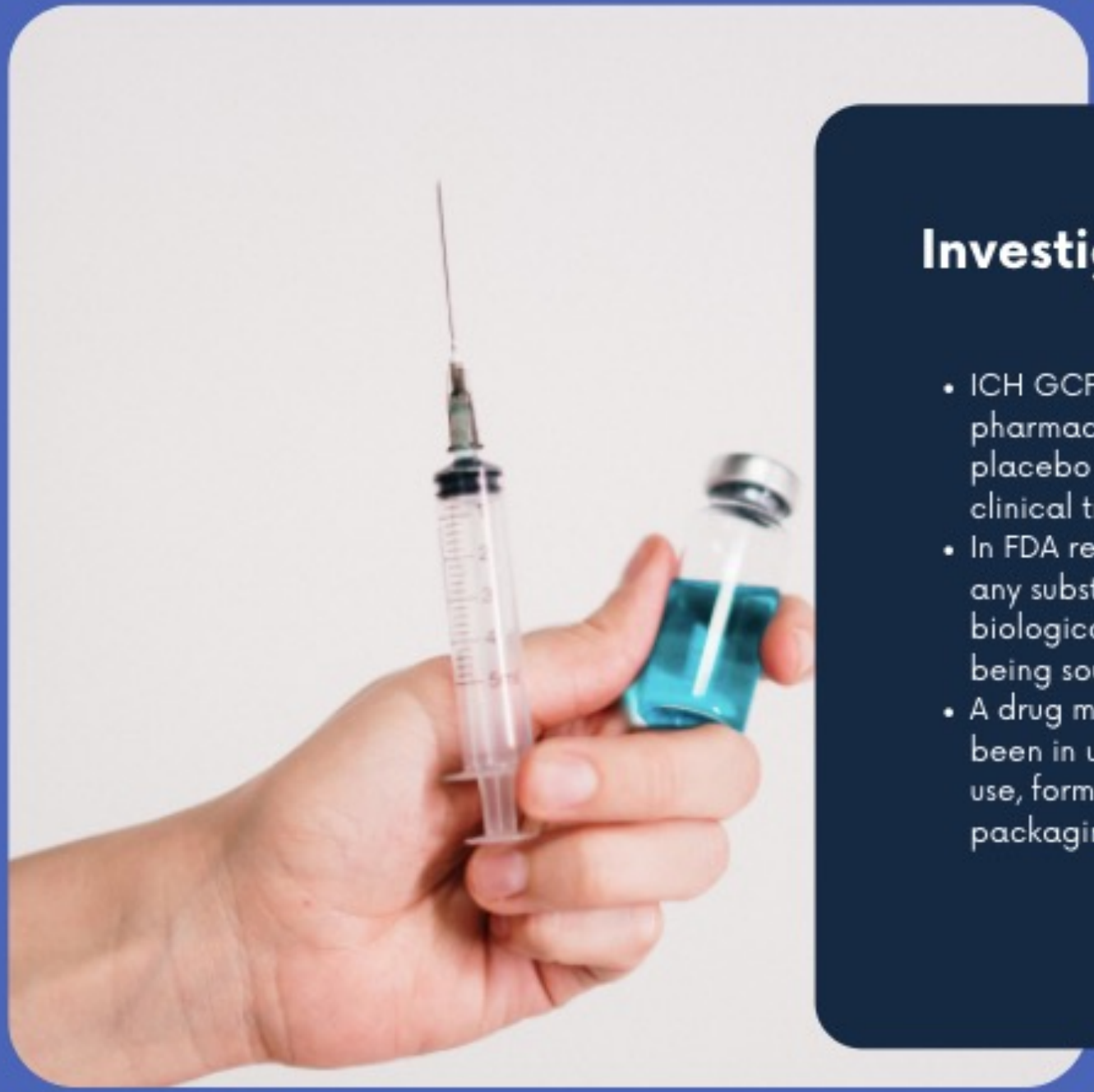
Penalties for research misconduct may include termination of employment, suspension or termination of a research grant, and suspension or debarment from receiving federal funds.

Roles and Responsibilities

- Good Clinical Practice (GCP) guidelines specifically define the responsibilities of the Sponsor and Principal Investigator of a clinical study.
- The ultimate responsibility for the quality and integrity of the trial data always resides with the Sponsor although some obligations of the sponsor maybe delegated to a partner organization or contract research organization (CRO).
- The Principal Investigator (PI) is responsible for the conduct of a clinical study at a research site and retains ultimate responsibility even if specific tasks are delegated to other site research staff.

Recruitment and Retention

- Recruitment of participants may not begin until the Institutional Review Board (IRB) has approved the protocol, informed consent documents, and proposed recruitment and retention strategies.
- Advertisements, fliers, and brochures that are prepared to recruit potential participants and inform them about a study are considered part of the informed consent process. As such, they must be reviewed and approved by the IRB (see ICH GCP 3.1.2).
- Recruitment for a study has two major elements:
  - Defining a population of appropriate participants to answer the research question.
  - Recruiting appropriate participants in an ethical manner.



Investigational New Drugs

- ICH GCP refers to an Investigational Product as a pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial.
- In FDA regulations, an investigational new drug is any substance (such as a drug, vaccine, or biological product) for which FDA approval is being sought.
- A drug may be considered "new" even if it has been in use for years if a change is proposed in its use, formulation, route of administration, or packaging.

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